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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,036	04/02/2004	Eric R. First	17675 (BOT)	2222

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,036	FIRST, ERIC R.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/04*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are pending.

Information Disclosure Statement

1. The information disclosure statement filed May 27, 2004 has been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 3 recites the limitation "is treated by increasing pigmentation" in an effort to further limit claim 2, but the step of increasing pigmentation does not find antecedent basis in the *already existing* skin disorder. There is insufficient antecedent basis for this limitation in the claim. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

4. Claim 4 recites the limitation "is treated by decreasing pigmentation" in an effort to further limit claim 2, but the step of decreasing pigmentation does not find antecedent basis in the *already existing* skin pigmentation disorder. There is insufficient antecedent basis for this limitation in the claim. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are

incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

5. Claim 7 recites the limitation "is treated by reducing a size of the melanin influenced affliction" in an effort to further limit claim 1, but the step of "reducing a size" lacks antecedent basis in claim 1 which does not recite the term "size", nor the step of "reducing", nor the term "influenced". There is insufficient antecedent basis for this limitation in the claim. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

6. Claim 10 recites the limitation "wherein the hair color is altered by decreasing the amount of pigmentation in the hair" in an effort to further limit claim 1, but the step of "decreasing" lacks antecedent basis in claim 1. The term "hair color" also lacks antecedent basis in claim 1 which recites the term "skin". There is insufficient antecedent basis for these limitations in the claim. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-6, 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by M. Rodriguez Vazquez et al (2002)

9. Vasquez et al disclose the instantly claimed method, the method comprising the step of:

Instant claims 1-6 and 14: Administering (subepidermal injection equal to subcutaneous administration) botulinum toxin (see page 154, col. 2, full paragraph at bottom of column) to a hyperpigmented area (see page 154, col. 1, paragraph 4) of patient skin (see page 154, "Case Report), wherein the patient had general pains (see page 154, col. 1, paragraph 3, last sentence of paragraph). The affected area had slight hyper-pigmentation in combination with hair, the naevus skin disorder being located

on the patient's lower back (see Figure 1, photographic image, page 154) which was found to evidence ductal hyperplasia and dilated coils without epidermal changes (see Figure 2).

Instant claims 11-12: the botulinum toxin administered was Botox, which is botulinum toxin A.

Instant claim 13: 2 U/injection (see page 155, col. 1, first paragraph) was administered which falls within the recited range of about 1 unit to about 3,000 units.

The reference inherently anticipates the instantly claimed invention as now claimed as Vasquez et al carried the identical methods step, wherein botulinum toxin was administered to a hyperpigmented region of skin.

10. Claims 8-9 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Maurer (PG-Pub 2002/0028765 A1, published March 7, 2002).

Mauer discloses the instant claimed invention directed to a method that comprises the step of:

Administering botulinum toxin to the hair of a patient (see abstract, title, [0019-0022]).

Mauer carries out the instantly claimed methods step of administering botulinum toxin to the hair of a patient and therefore inherently anticipates the instantly claimed invention as now claimed. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al.,

205 USPQ 594 Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art≅.

11. Claims 1-6,8-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Waugh et al (US PG-Pub 2004/0220100 A1, filing date March 3, 2004).

Waugh et al disclose the instantly claimed invention directed to a method, the method comprising the step of:

Instant claims 1-6,7-10: Administering a botulinum toxin to the skin of a patient (see abstract "transdermal delivery; see page 16, [0146 "applied topically to the skin at a location"]; [0145 "released into the skin"]), wherein the botulinum toxin is administered in a composition that provides for lightening, darkening or coloring agents for the skin , other tissues(see page 16, [0144, col. 2, lines 1-3 and lines 12-13), to include hair follicles associated with skin (see page 3, [0016, second half of paragraph]) to which the composition is applied to include preventing or reducing acne (see page 5, col. 1, line 1).

Instant claim 11-12: the botulinum toxin is disclose to comprise any one of the known botulinum toxins (types A-G: see page 2, [0010], and specifically botulinum toxin A (see [0013, page 2, col. 2, last two lines]; page 13, col. 1, lines 1-3).

Instant claim 13: the dosage being from about 1 U to about 10,000 U (see page 16, [0141, col. 1]), which includes the instantly claimed range of about 1 U to about 3,000 U.

Instant claim 14: the administration may be topical or subcutaneous (see page 18, [0165, col. 1, lines 1-2]). The reference anticipates the instantly claimed invention.

12. Claims 1-2,4-7, 11-12, 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Pastan et al (US PG-Pub 2004/0087772 A1).

13. Pastan et al disclose the instantly claimed invention directed to a method that comprises the step of:

Instant claims 1-2, **Administering** botulinum toxin (see page 4, [0022 "botulinum toxins A through F"]; page 7, [0064, "botulinum toxin"]) to the skin (see page 9, [0099, "subcutaneous", "topical, transdermal, or transmucosal" administration) of a patient (see page 7, [0054, "animal or human disease"], page 9, [0097, "mammal"] and [0101 "subject"]) to inhibit melanoma (see page 4, col. 1, near bottom of paragraph: "melanoma cells") cancer, a type of pigmentation disorder (see claims 85-89, and claims 70-77).

Instant claims 2, 4-5: By killing melanoma cells, which by definition include dark brown to black cells, the administered botulinum toxin influences a skin pigmentation of the melanoma skin pigmentation disorder affliction.

Instant claims 6-7: The killing the melanoma cells with the botulinum toxin, the pigmentation affliction will result in the size of the pigmented region being reduced in size.

Instant claims 11-12: the botulinum toxin being a botulinum toxin A through F (see page 4, [0022]).

Instant claim 14: topical or subcutaneous administration (see page 9, [0099]).

The reference inherently anticipates the instantly claimed invention. Since the Office

does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.'

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

15. Aoki et al (Us Pat. 6,896,886) is cited to show the administration of botulinum toxin to the skin of a human (see col. 10, claim 2) to treat a condition of the skin associated with pain (see title and claims1-2).
16. US Pat. 6,299,893 is cited to show the administration of botulinum toxin to prevent hair loss and to stimulate hair growth.
17. US Pat. 6,688,311 is cited to show the administration of botulinum toxin to skin.
18. US Pat. 6,447,787 is cited to show the administration of botulinum toxin to a skin wound of the face, administered subcutaneously (see claims 1-20).
19. US Pat. 5,766,605 is cited to show administration of botulinum toxin to the skin of a human (see claim 13).
20. PG-Pub US 2004/02113815 A1 is cited to show the administration of botulinum toxin to the skin of a patient (see abstract and entire document).

21. Binder (US Pat. 5,714,468) is cited to show administration of botulinum toxin to the head.
22. Binder (US Pat. 5,670,484 and EP 0845267 A1) are cited to show the administration of botulinum toxin to the skin of a patient to aid in the resolution of skin lesions, the lesions being associated with pigmentation (for example: pityriasis rosea, see col. 5, lines 24-26) and discomfort (see col. 5, lines 51-58).
23. CA 2494473 is cited to show compositions for topical and transdermal administration of an active agent, the agent being botulinum toxin (see page 24, claims 7-8, 13-15 and 32 "anti-aging composition)
24. Donovan (PG-Pub 20050031648 A1) is cited to show the administration of botulinum toxin to melanoma skin cancer (see abstract and title)
25. KR 2003005078 (abstract, English only), is cited to show a composition that comprises Botox that prevents aging of the skin.
26. Sherman et al (US Pat. 6,451,249) is cited to show a device and method for adding pigment and botulinum toxin to the skin of a subject (see summary of invention and claims.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
July 13, 2005

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